IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BECTON, DICKINSON AND COMPANY, GENEOHM SCIENCES CANADA, INC. and HANDYLAB, INC.,	)	
Plaintiffs,	)	C.A. No. 19-1126-LPS
v.	)	**DEMAND FOR JURY TRIAL**
NEUMODX MOLECULAR, INC., QIAGEN N.V., QIAGEN GMBH, QIAGEN NORTH AMERICAN HOLDINGS, INC., and QIAGEN LLC,	)	**FILED UNDER SEAL**
Defendants.	)	

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' SECOND AND SUPPLEMENTAL COMPLAINT

Defendants NeuMoDx Molecular, Inc. ("NeuMoDx"), Qiagen GmbH, and Qiagen North American Holdings, Inc. ("Qiagen NA") (Qiagen GmbH, and Qiagen NA shall be referred to herein jointly as "Qiagen"[1] and NeuMoDx, Qiagen GmbH, and Qiagen NA shall be referred to herein collectively as ("Defendants")) answer Plaintiffs Becton, Dickinson and Company, GeneOhm Sciences Canada, Inc. (jointly "BD"), and HandyLab, Inc.'s ("HandyLab" and collectively with BD, "Plaintiffs") Second Amended and Supplemental Complaint and hereby allege as follows:

NATURE OF THE ACTION

1. No response is necessary for this statement.

2. Defendants admit that Plaintiffs brought the present action, but deny that they have infringed any of Plaintiffs' patent rights, including the Asserted Patents, or that Plaintiffs

[1] Plaintiffs' Second Amended and Supplemental Complaint has been dismissed to the extent it concerned Qiagen N.V. and Qiagen LLC. D.I. Nos. 164 and 159. Neither Qiagen N.V. nor Qiagen LLC is a party to this lawsuit. They do not join any part of this pleading and nothing in this pleading should be interpreted as applying to or being submitted on behalf of either Qiagen N.V. or Qiagen LLC.

are entitled to any relief.

THE PARTIES

3. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 3, and therefore deny them leaving Plaintiffs to their proofs.

4. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 4, and therefore deny them leaving Plaintiffs to their proofs.

5. Defendants admit that NeuMoDx is a corporation organized and existing under the laws of Delaware, with a place of business at 1250 Eisenhower Place, Ann Arbor, Michigan 48108-3281. Defendants admit that NeuMoDx was acquired by Qiagen on September 17, 2020, and is related to and/or a subsidiary of Qiagen N.A. and Qiagen N.V.

6. The allegations in paragraph 6 are specific to Qiagen N.V. Qiagen N.V. has been dismissed from this lawsuit. D.I. Nos. 164 and 159. Therefore, no response is necessary for this paragraph 6.

7. Qiagen GmbH admits that it is a corporation organized and existing under the laws of Germany, with a principal place of business at QIAGEN Strasse 1, 40724 Hilden, Germany, and that it is a subsidiary of Qiagen N.V.

8. Qiagen NA admits that it is a corporation organized under the laws of California with a principal place of business at 19300 Germantown Road, Germantown, Maryland 20874. Qiagen NA and NeuMoDx admit that they are subsidiaries of Qiagen N.V.

9. The allegations in paragraph 9 are specific to Qiagen LLC. Qiagen LLC has been dismissed from this lawsuit. D.I. Nos. 164 and 159. Therefore, no response is necessary for this paragraph 9.

FACTUAL ALLEGATIONS

Background

10. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 10, and therefore deny them leaving Plaintiffs to their proofs.

11. Admitted as to NeuMoDx. Qiagen is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 11, and therefore denies them leaving Plaintiffs to their proofs.

12. Exhibits 7 and 8 speak for themselves and therefore no response is required on allegations based upon those documents. Defendants deny that BD was granted an exclusive license to HandyLab's patented technologies as reflected in the Asserted Patents. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in paragraph 12, and therefore deny them leaving Plaintiffs to their proofs.

13. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 13, and therefore denies same leaving Plaintiffs to their proofs.

NeuMoDx

14. NeuMoDx admits that Jeff Williams founded Molecular Systems Corp. in 2012, and that Molecular Systems Corp. changed its name to NeuMoDx. NeuMoDx admits that Sundaresh Brahmasandra served as Vice President of Research and Development Assay Development at BD after the HandyLab acquisition, but that Brahmasandra joined NeuMoDx as President in 2012 only after requesting and obtaining express written permission from BD. NeuMoDx admits that Williams and Brahmasandra are each named inventors on some of patents asserted in the Complaint, and are now aware of the Asserted Patents. NeuMoDx denies the remaining allegations in paragraph 14. The allegations in paragraph 14 are directed

at NeuMoDx. Qiagen GmbH and Qiagen NA are without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 14, and therefore deny same leaving Plaintiffs to their proofs.

15. Denied.

16. NeuMoDx admits that it commissioned a review of patents no later than 2017 before making, using, selling or offering to sell NeuMoDx's molecular diagnostic products, which information was provided to BD on a confidential basis solely for the purpose of BD's consideration of NeuMoDx when NeuMoDx was being offered for sale, and which public disclosure by BD violates that obligation of confidentiality. NeuMoDx denies the remaining allegations in paragraph 16. The allegations in paragraph 16 are directed at NeuMoDx. Qiagen GmbH and Qiagen NA are without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 16, and therefore deny same leaving Plaintiffs to their proofs.

QIAGEN

17. Defendants incorporate their responses to each of the paragraphs above and below as though fully set forth herein.

18. Qiagen GmbH and Qiagen N.A. are related entities that work in the molecular testing space. Exhibit 94 speaks for itself and therefore no response is required on allegations based upon that document. Qiagen denies the remaining allegations in paragraph 18. The allegations in paragraph 18 are directed at Qiagen. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 18, and therefore denies same leaving Plaintiffs to their proofs.

19. Exhibits 95 and 96 speak for themselves and therefore no response is required on allegations based upon those documents. Qiagen and NeuMoDx admit that they released a

statement on September 17, 2018, which "announced a strategic partnership to commercialize two new fully integrated systems for automation of PCR (polymerase chain reaction testing)." Defendants admit that the statement referred to an "agreement" where "Qiagen will initially distribute the NeuMoDx 288 (high-throughput version) and NeuMoDx 96 (mid-throughput version) in Europe and other major markets worldwide outside of the United States." Defendants admit that the statement also says, "NeuMoDx will cover the United States directly." Defendants admit that Qiagen and NeuMoDx entered an agreement under which Qiagen acquired a 19% stake in NeuMoDx with an option to acquire the remaining NeuMoDx shares. Qiagen and NeuMoDx admit that Qiagen acquired the remaining stock on September 17, 2020. Except as admitted, Defendants deny the remaining allegations in paragraph 19.

20. Denied.

21. Exhibits 97, 98, 99, and 100 speak for themselves and therefore no response is required on allegations based upon those documents. Qiagen admits that it has distributed and has supported certain NeuMoDx products outside the United States. Qiagen admits that outside the U.S. it displayed and was (and continues to be) a distributor of certain NeuMoDx Systems after September 2018. Qiagen admits that https://go.qiagen.com/NeuMoDx is a subpage within the https://go.qiagen.com website. To the extent not otherwise admitted, Qiagen denies (or lacks sufficient to form a belief as to the truth of the remaining allegations and therefore denies) the remaining allegations. The allegations in paragraph 21 are directed at Qiagen. NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 21, and therefore denies same leaving Plaintiffs to their proofs.

22. Qiagen admits that it conducted due diligence on NeuMoDx prior to its acquisition. Qiagen admits that it contacted BD in 2018 and further filed petitions for *inter partes*

review against U.S. Patent Nos. 7,998,708 and 8,323,900 (the "IPRs") in December 2018. To the extent not otherwise admitted, Qiagen denies the remaining allegations of this paragraph. The allegations in paragraph 22 are directed at Qiagen. NeuMoDx admits that Qiagen filed the aforementioned IPRs in December 2018. Otherwise, NeuMoDx is without knowledge sufficient to form a belief as to the truth of the allegations in paragraph 22, and therefore denies same leaving Plaintiffs to their proofs.

23. Defendants admit that NeuMoDx was ordered to attend a mediation conference on October 23, 2020, pursuant to an Order Governing Telephonic or Video Mediation Conferences and Mediation Statements which was entered on September 2, 2020 (the "Order"). The Order speaks for itself and therefore no response is required on allegations based upon the Order. Paragraph 8 of the Order states:

> The contents of the mediation statements and the mediation teleconference discussions, including any resolution or settlement, shall remain confidential, shall not be used in the present litigation nor any other litigation (whether presently pending or filed in the future), and shall not be construed as nor constitute an admission. Breach of this provision shall subject the violator to sanctions.

Defendants believe that Plaintiffs allegations in this paragraph violate the above provision of the Order and Defendants therefore will not respond to them because doing so would further violate the Court's Order.

24. Admitted.

25. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore denies same leaving Plaintiffs to their proofs.

26. Denied.

THE ASSERTED PATENTS

27. Defendants incorporate each of responsive paragraphs above and below as though fully set forth herein.

28. Defendants admit that U.S. Patent No. 8,273,308 (the "'308 Patent") entitled "Moving Microdroplets in a Microfluidic Device" issued on September 25, 2012. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

29. Defendants admit that U.S. Patent No. 8,703,069 (the "'069 Patent"), entitled "Moving Microdroplets in a Microfluidic Device" issued on April 22, 2014. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

30. Defendants admit that U.S. Patent No. 7,998,708 (the "'708 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" issued on August 16, 2011. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

31. Defendants admit that U.S. Patent No. 8,323,900 (the "'900 Patent"), entitled "Microfluidic System for Amplifying and Detecting Polynucleotides in Parallel" issued on December 4, 2012. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

32. Defendants admit that U.S. Patent No. 8,415,103 (the "'103 Patent"), entitled "Microfluidic Cartridge" issued on April 9, 2013. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

33. Defendants admit that U.S. Patent No. 8,709,787 (the "'787 Patent"), entitled "Microfluidic Cartridge and Method of Using Same" issued on April 29, 2014. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

34. Defendants admit that U.S. Patent No. 10,494,663 (the "'663 Patent"), entitled "Method for Processing Polynucleotide-Containing Samples" issued on December 3, 2019. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

35. Defendants admit that U.S. Patent No. 10,364,456 (the "'456 Patent"), entitled "Method for Processing Polynucleotide-Containing Samples" issued on July 30, 2019. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

36. Defendants admit that U.S. Patent No. 10,443,088 (the "'088 Patent"), entitled "Microfluidic Cartridge and Method of Using Same" issued on October 15, 2019. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a

belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

37. Defendants admit that U.S. Patent No. 10,604,788 (the "'788 Patent"), entitled "System for Processing Polynucleotide-Containing Samples" issued on March 31, 2020. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

38. Defendants admit that U.S. Patent No. 10,625,261 (the "'261 Patent"), entitled "Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples" issued on April 29, 2014. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

39. Defendants admit that U.S. Patent No. 10,625,262 (the "'262 Patent"), entitled "Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples" issued on April 21, 2020. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

40. Defendants admit that U.S. Patent No. 10,632,466 (the "'466 Patent"), entitled "Integrated Apparatus for Performing Nucleic Acid Extraction and Diagnostic Testing on Multiple Biological Samples" issued on April 28, 2020. Defendants deny it was duly and legally issued. Defendants are without knowledge sufficient to form a belief as to the truth of

the remaining allegations in this paragraph, and therefore deny the same leaving Plaintiffs to their proofs.

41. Defendants admit that Williams, Brahmasandra and other NeuMoDx employees are named as inventors on some of the Asserted Patents. Defendants admit that as co-inventors of the '708 and '900 patents, Williams and Brahmasandra had knowledge of the '708 and '900 patents at some point after the' 708 patent issued on August 16, 2011 and the '900 patent issued on December 4, 2012. The citation of some of the Asserted Patents during the prosecution of NeuMoDx's patents, IPR2019-00488 and IPR2019-00490 proceedings, and Exhibit 9 speak for themselves and therefore no response is required on allegations based upon those documents. NeuMoDx admits that it commissioned a review of patents no later than 2017 before making, using, selling or offering to sell NeuMoDx's molecular diagnostic products, which information was provided to BD on a confidential basis solely for the purpose of BD's consideration of NeuMoDx when NeuMoDx was being offered for sale, and which public disclosure by BD violates that obligation of confidentiality. NeuMoDx admits that BD included the '663, '456, '088 and '788 patents for the first time in disclosures dated April 13, 2020. NeuMoDx denies the remaining allegations in paragraph 41. The allegations in this paragraph are directed at NeuMoDx. Qiagen lacks knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies the same leaving Plaintiffs to their proofs.

42. Exhibit 101 speaks for itself and therefore no response is required on allegations based upon that document. Qiagen admits that it conducted certain due diligence into NeuMoDx's technology as of or around September 2018. Qiagen admits that by this same timeframe it was aware of certain of the Asserted Patents and/or patent applications resulting in the Asserted Patents. Qiagen admits that it was aware of the '708 and '900 Patents by

December 2018, when it filed the IPRs against those patents and further that it was aware of each of the Asserted Patents by October 23, 2020. Plaintiffs reference to details of the mediation is violative of the Court's Order. *See infra* ¶ 23. Defendants deny the remaining allegations in this paragraph.

DEFENDANTS' INFRINGING PRODUCTS

43. Defendants incorporate each of the paragraphs above and below as though fully set forth herein.

44. Denied.

45. Defendants admit that NeuMoDx manufactures and sells in the United States molecular diagnostic systems, including NeuMoDx™ 288 Molecular System (Product Code 500100) and NeuMoDx™ 96 Molecular System (Product Code 50200). Defendants admit that NeuMoDx also manufactures and sells, or has manufactured and/or sold, the instruments, consumables, accessories, test strips and reagents, listed in paragraph 33, in the United States although not all products have an accurate product code. Qiagen admits that Qiagen GmbH sells molecular diagnostic systems and sells and/or distributes outside the United States the NeuMoDx™ 288 Molecular System (Product Code 500100) and NeuMoDx™ 96 Molecular System (Product Code 50200), as well as certain related consumables, accessories, test strips, and reagents. Defendants deny the remaining allegations in paragraph 45.

46. Defendants admit that certain of NeuMoDx's products are described on a website (https://go.qiagen.com/NeuMoDx#learnmore). Defendants deny the remaining allegations in paragraph 46.

47. NeuMoDx admits that its website links or linked to videos showing operation of the NeuMoDx™ 288 and NeuMoDx™ 96 Molecular Systems. NeuMoDx admits that its

website links or linked to Vimeo hyperlinks https://vimeo.com/281470603 and https://vimeo.com/299307936. Defendants deny the remaining allegations in this paragraph 47.

48. Defendants admit that a webpage located at (https://go.qiagen.com/NeuMoDxVirtualShowcase) includes a "Discovery NeuMoDx at our virtual showcase," which describes a webinar that purports to discuss "the NeuMoDx 96 and NeuMoDx 288 platforms." Defendants deny the remaining allegations in this paragraph 48.

49. Exhibit 19 speaks for itself and therefore no response is required on allegations based upon that document. Defendants admit the remaining allegations in this paragraph 49.

JURISDICTION AND VENUE

50. Defendants incorporate each of the paragraphs above and below as though fully set forth herein.

51. Paragraph 51 states a legal conclusion and therefore no response is required. Defendants do not dispute subject matter jurisdiction for purposes of this lawsuit only.

52. Paragraph 52 includes legal conclusions that require no response. NeuMoDx admits that this Court may exercise personal jurisdiction over NeuMoDx for purposes of this case only. NeuMoDx denies the remaining allegations in paragraph 52.

53. Paragraph 53 includes legal conclusions that require no response. Qiagen GmbH and Qiagen N.A. do not dispute that this Court may exercise personal jurisdiction over them for purposes of this case only. (*See* D.I. 159, ¶ 5.) Qiagen GmbH and Qiagen N.A. deny the remaining allegations in paragraph 53.

54. The allegations set forth in paragraph 54 are directed at Qiagen N.V. Qiagen N.V. has been dismissed from this lawsuit and therefore no response is required with respect to the allegations in paragraph 54. (*See* D.I. 174.)

55. Paragraph 55 includes legal conclusions that require no response. Qiagen GmbH does not dispute that this Court may exercise personal jurisdiction over it for purposes of this case only. (*See* D.I. 159, ¶ 5.) Qiagen GmbH admits that it sells and/or distributes certain NeuMoDx products outside the United States. Qiagen GmbH admits that NeuMoDx has asserted an affirmative defense in this litigation based on a license agreement between Qiagen GmbH and HandyLab and that such license says it shall be construed and enforced in accordance with the laws of the State of Delaware. Qiagen GmbH denies the remaining allegations in paragraph 55.

56. Paragraph 56 includes legal conclusions that require no response. Certain of the allegations set forth in paragraph 56 are directed at Qiagen N.V. Qiagen N.V. has been dismissed from this lawsuit and therefore no response is required with respect to those allegations in paragraph 56. (*See* D.I. 174.) Certain of the allegations violate the Court's Order and will not be responded to for that reason. *See infra* Paragraph 8. Qiagen GmbH does not dispute that this Court may exercise personal jurisdiction over it for purposes of this case only. (*See* D.I. 159, ¶ 5.) Qiagen GmbH denies the remaining allegations in paragraph 56.

57. Paragraph 57 includes legal conclusions that require no response. Certain of the allegations set forth in paragraph 56 are directed at Qiagen N.V. Qiagen N.V. has been dismissed from this lawsuit and therefore no response is required with respect to those allegations in paragraph 56. (*See* D.I. 174.) Qiagen GmbH does not dispute that this Court may exercise personal jurisdiction over it for purposes of this case only. (*See* D.I. 159, ¶ 5.) Qiagen GmbH denies the remaining allegations in paragraph 57.

58. Paragraph 58 includes legal conclusions that require no response. Qiagen NA admits that it executed a merger agreement with NeuMoDx, which speaks for itself. Qiagen NA

refers to and incorporates by reference the following IPR papers, which speak for themselves: IPR2019-00488, Paper 1; IPR2019-01493, Paper 2; IPR2020-01083, Paper 2; IPR2020-01091, Paper 2; IPR2019-00490, Paper 1; IPR2019-01494, Paper 2; IPR2020-01133, Paper 2; IPR2020-01136, Paper 2; IPR2020-01100, Paper 3; IPR2020-01095, Paper 2; IPR2020-01132, Paper 2; IPR2020-01137, Paper 2; IPR2021-00251, Paper 2; IPR2021-00250, Paper 2; and IPR2021-00253, Paper 2. Qiagen NA denies the remaining allegations in paragraph 58.

59. The allegations set forth in paragraph 59 are directed at Qiagen LLC. Qiagen LLC has been dismissed from this lawsuit and therefore no response is required with respect to the allegations in paragraph 59. (*See* D.I. 174.)

60. Denied.

61. Exhibits 99 and 101 speak for themselves and therefore no response is required on allegations based upon those documents. Certain of the allegations set forth in paragraph 61 are directed at Qiagen N.V. Qiagen N.V. has been dismissed from this lawsuit and therefore no response is required with respect to those allegations. (*See* D.I. 174.) Defendants deny the remaining allegations in paragraph 61.

62. Exhibit 101 speaks for itself and therefore no response is required on allegations based upon that document. Certain of the allegations set forth in paragraph 62 are directed at Qiagen LLC. Qiagen LLC has been dismissed from this lawsuit and therefore no response is required with respect to those allegations. (*See* D.I. 174.) Defendants deny the remaining allegations in paragraph 62.

63. Exhibits 102-05 and D.I. 90 from the pleadings from No. 16-cv-02788-WHA litigation speak for themselves and therefore no response is required on allegations based upon those documents. Certain of the allegations set forth in paragraph 63 are directed at Qiagen

N.V. and Qiagen LLC. Qiagen N.V. and Qiagen LLC have been dismissed from this lawsuit and therefore no response is required with respect to those allegations. (*See* D.I. 174.) Certain of the allegations violate the Court's Order. *See infra* Paragraph 8. Defendants deny the remaining allegations in paragraph 63.

64. Exhibits 104-106 speak for themselves and therefore no response is required on allegations based upon those documents. Certain of the allegations set forth in paragraph 64 are directed at Qiagen N.V. and Qiagen LLC. Qiagen N.V. and Qiagen LLC have been dismissed from this lawsuit and therefore no response is required with respect to those allegations. (*See* D.I. 174.) Qiagen NA admits that it has a place of business at 19300 Germantown Road, Germantown, Maryland 20874. Qiagen NA and NeuMoDx admit that NeuMoDx is sometimes referred to as "a Qiagen company." Qiagen NA admits that it executed a merger agreement with NeuMoDx, which speaks for itself. Qiagen NA refers to and incorporates by reference the following IPR papers, which speak for themselves: IPR2019-00488, Paper 15; IPR2019-01493, Paper 2; IPR2020-01083, Paper 2; IPR2020-01091, Paper 2; IPR2019-00490, Paper 15; IPR2019-01494, Paper 2; IPR2020-0113, Paper 2; IPR2020-01136, Paper 2; IPR2020-01100, Paper 3; IPR2020-01095, Paper 2; IPR2020-01132, Paper 2; IPR2020-01137, Paper 2; IPR2021-00251, Paper 2; IPR2021-00250, Paper 2; and IPR2021-00253, Paper 2. Defendant deny or lack sufficient information to admit or deny, and therefore deny, the remaining allegations in this paragraph 64.

65. Paragraph 65 includes legal conclusions that require no response. Certain of the allegations set forth in paragraph 65 are directed at Qiagen N.V. and Qiagen LLC. Qiagen N.V. and Qiagen LLC have been dismissed from this lawsuit and therefore no response is required with respect to those allegations. (*See* D.I. 174.) Defendants do not dispute that this Court may

exercise personal jurisdiction over them for purposes of this case only. (*See* D.I. 159, ¶ 5.) Defendants deny the remaining allegations in paragraph 65.

66. Defendants incorporate each of the paragraphs above and below as though fully set forth herein. Paragraph 66 states a legal conclusion and therefore no response is required. Certain of the allegations set forth in paragraph 66 are directed at Qiagen N.V. and Qiagen LLC. Qiagen N.V. and Qiagen LLC have been dismissed from this lawsuit and therefore no response is required with respect to those allegations. (*See* D.I. 174.) Defendants do not dispute venue for purposes of this case only. Defendants deny the remaining allegations in paragraph 66.

COUNT 1

(INFRINGEMENT OF THE '308 PATENT)

67. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

COUNT 2

(INFRINGEMENT OF THE '069 PATENT)

78. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

COUNT 3

(INFRINGEMENT OF THE '708 PATENT)

87. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

88. Denied.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

COUNT 4

(INFRINGEMENT OF THE '900 PATENT)

97. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

98. Denied

99. Denied.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

COUNT 5 (INFRINGEMENT OF THE '103 PATENT)

108. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

109. Denied.

110. Denied.

111. Denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

COUNT 6 (INFRINGEMENT OF THE '787 PATENT)

118. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

126. Denied.

COUNT 7 (INFRINGEMENT OF THE '663 PATENT)

127. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

128. Denied.

129. Denied.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

135. Denied.

COUNT 8 (INFRINGEMENT OF THE '456 PATENT)

136. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

137. Denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

COUNT 9 (INFRINGEMENT OF THE '088 PATENT)

145. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

146. Denied.

147. Denied.

148. Denied.

149. Denied.

150. Denied.

151. Denied.

152. Denied.

153. Denied.

COUNT 10 (INFRINGEMENT OF THE '788 PATENT)

154. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

155. Denied.

156. Denied.

157. Denied.

158. Denied.

159. Denied.

160. Denied.

161. Denied.

162. Denied.

COUNT 11 (INFRINGEMENT OF THE '261 PATENT)

163. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

164. Denied.

165. Denied.

166. Denied.

167. Denied.

168. Denied.

169. Denied.

170. Denied.

171. Denied.

COUNT 12 (INFRINGEMENT OF THE '262 PATENT)

172. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

173. Denied.

174. Denied.

175. Denied.

176. Denied.

177. Denied.

178. Denied.

179. Denied.

180. Denied.

COUNT 13 (INFRINGEMENT OF THE '466 PATENT)

181. Defendants incorporate and reference its answers to the above and below paragraphs and incorporate them as though fully set forth herein.

182. Denied.

183. Denied.

184. Denied.

185. Denied.

186. Denied.

187. Denied.

188. Denied.

189. Denied.

AFFIRMATIVE DEFENSES

Defendants deny that Plaintiffs are entitled to any of their prayer for relief (a)-(g).

AFFIRMATIVE DEFENSES

First Affirmative Defense
(Invalidity)

The '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including for the failure to meet one or more of the requirements for patentability as specified in at least 35 U.S.C. §§ 101, 102, 103, and/or 112, as detailed below in Defendants' counterclaims.

Second Affirmative Defense
(Non-Infringement)

Defendants have not infringed, contributed to the infringement of, induced the infringement of, or infringed under 35 U.S.C. § 271(f) any valid claim of the asserted '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466, either directly or indirectly, literally or under the doctrine of equivalents, as detailed below in NeuMoDx's counterclaims.

Third Affirmative Defense
(Equitable Estoppel/Acquiescence/Waiver/Unclean Hands)

Plaintiffs are barred, in whole or in part, from recovering the relief sought in this action by the doctrine of equitable estoppel, acquiescence, waiver and/or unclean hands.

BD acquired HandyLab on November 19, 2009. Prior to the acquisition Jeff Williams was the CEO of HandyLab, and Sundaresh Brahmasandra was the Vice President of Product Development. Williams was not employed by BD after the acquisition but assisted with the transition for approximately one week at the request of BD and had a one year non-compete agreement with BD. Brahmasandra remained with BD as an employee until March 2011.

Brahmasandra's employment contract included a 2-year post-employment non-compete provision.

Williams continued his relationship with BD after the sale of HandyLab. In 2011, Williams, as CEO, facilitated the sale of Accuri Cytometers to BD. Also, in early 2011, and clear of his non-compete obligations, Williams contemplated a new company to pursue nucleic acid-based testing (molecular diagnostics) for higher throughput labs. Williams believed that an unmet need existed with a segment of customers in the molecular diagnostics market who desired a system that did not use unitized reagents and offered higher throughput, larger capacity, and more rapid turnaround time with better ease of use for medium to large hospital central laboratories and clinical reference labs. Williams formed Molecular Systems Corporation (MSC), the predecessor of NeuMoDx.

After completing his employment agreement with BD and BD's announcement that it would close the Ann Arbor facility, Brahmasandra left BD. Brahmasandra worked for another life-sciences company in Ann Arbor, and was subsequently invited to join MSC. However, Brahmasandra's non-compete agreement had not expired. Accordingly, in late 2011, Williams and Brahmasandra contacted senior executives at BD and shared Williams' intentions to actively pursue, with the support of venture capital, a startup nucleic acid testing systems company. Brahmasandra informed BD that he was interested in joining MSC, but that he was prevented from doing so because of the non-compete agreement with BD. Brahmasandra requested a waiver of his non-compete agreement to work with Williams at MSC to develop a nucleic acid-based system for performing rapid identification.

On December 21, 2011, BD, through a senior executive responsible for the diagnostics business, granted Brahmasandra's request based upon Williams and Brahmasandra's "good track

record." In return, BD asked for access to review MSC's technology for "future potential partnership interest." BD and Brahmasandra entered into an "Amendment to Employment Agreement" on February 23, 2012. BD acknowledged that "Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation", and that the "Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement." The Amendment required Brahmasandra to use "commercially reasonable efforts" to schedule a meeting with "representatives of BD's exploratory technology group for the purpose of providing additional information about the Proposed Business, subject to the execution and delivery of a customary non-disclosure agreement… ."

Brahmasandra and MSC relied on BD's representations, and Brahmasandra complied with his obligations. On several occasions during 2012 and 2013, NeuMoDx shared its business purposes, system architecture, technology, patents/patent applications and financing/financing plans with BD under confidentiality. In July 2013, NeuMoDx inquired with a senior BD executive about BD's interest in participating in a venture financing round of NeuMoDx. NeuMoDx provided a two-page summary of its system and technology and informed BD that NeuMoDx "had developed technology combining the best attributes of both integrated cartridge and microplate-based, liquid handling system, with the resulting platform to offer improved ease of use, lower costs, and higher performance compared to other nucleic acid testing systems."

After 2013, NeuMoDx met with representatives of BD at least annually at industry trade shows at which NeuMoDx provided BD with demonstrations of the NeuMoDx products and answered questions about the technology. The last such meeting was at a trade show in April of

2019. BD explained to NeuMoDx that the meetings were intended to keep BD informed about NeuMoDx's technology in the event BD was interested in "partnership interests" or acquiring NeuMoDx. During the parties' meetings, NeuMoDx shared its technology, including confidential aspects of its technology, with BD. At no point from 2012 to December 2018 did BD ever suggest that any NeuMoDx product violates or infringes any BD patents, let alone the patents acquired by BD from HandyLab. Furthermore, on several occasions BD R&D personnel and executives commented on the uniqueness and novelty of the NeuMoDx products.

On December 21, 2018, BD's VP of Strategy & Business Development for BD Life Sciences contacted Williams to express concern regarding IPR petitions filed against BD's '708 and '900 patents. Williams assured BD that NeuMoDx was not involved in the IPR filings. Williams described the care taken by NeuMoDx to ensure that its products do not infringe third party patents, including those belonging to BD and HandyLab given the relationship between BD/HandyLab and NeuMoDx. Williams invited BD to Ann Arbor to see NeuMoDx's products. On February 4, 2019, Williams and Brahmasandra met with two executives from BD at NeuMoDx's facility in Ann Arbor. The parties focused their discussions on the IPRs, NeuMoDx's products and NeuMoDx's detailed explanation as why its products do not violate the '708 and '900 patents subject to the IPR petitions. The parties discussed trying to arrive at a reasonable resolution, but BD needed time to discuss internally.

In April of 2019, NeuMoDx spoke with BD again at a trade show, but BD had no updates from the parties' February 4, 2019 meeting. No further communication between NeuMoDx and BD occurred until after BD filed the complaint against NeuMoDx.

Upon information and belief, after portraying the parties' meetings as a way to foster potential collaborations between the parties', and encouraging NeuMoDx to share its confidential

product and technical information with BD to facilitate collaboration, BD is believed to have used NeuMoDx's confidential information against it to file the present Complaint.

Fourth Affirmative Defense
(Breach of Contract)

On February 23, 2012, BD and Brahmasandra entered into an "Amendment to Employment Agreement." BD agreed that "Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by Molecular Systems Corporation", and that the "Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement." BD has now breached the Amended Agreement with Brahmasandra and MSC/NeuMoDx, the intended third party beneficiary of the Agreement, by suing NeuMoDx for the very nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification activity that BD agreed Brahmasandra and MSC/NeuMoDx could engage in, as detailed below in NeuMoDx's counterclaims.

Fifth Affirmative Defense
(Lack of Notice)

The patent owner of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents failed to provide notice pursuant to 35 U.S.C. §287 prior to filing the original complaint. Plaintiffs failed to provide constructive notice of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents by marking any products covered by the patents. Likewise, Plaintiffs failed to provide actual notice of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents prior to filing the Complaint on June 18, 2019. Therefore, Plaintiffs cannot recover damages for any alleged infringement that

occurred prior to the filing of this case.

Sixth Affirmative Defense
(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim against Defendants upon which relief can be granted.

Seventh Affirmative Defense
(Improper Inventorship)

The '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, including for the failure to identify the proper inventive entity as specified in at least 35 U.S.C. § 101 and pre-AIA 35 U.S.C. § 102(f). The '261, '262 and '466 patents improperly omit inventors of the claimed subject matter, including Sundaresh Brahmasandra, Elizabeth Boutt and Patrick Duffy. The '308, '069, '103, '787 patents improperly omit inventors of the claimed subject matter, including Sundaresh Brahmasandra and Jeff Williams. The '456, '088, '788, '663 patents improperly list inventors who are not believed to have contributed to the claimed subject matter, including Theodore Springer. The '708 and '900 patents improperly omit inventors of the claimed subject matter, including Kerry Wilson and Patrick Duffy and Nikhil Padke.

Eighth Affirmative Defense
(License)

Qiagen GmbH and HandyLab entered into a License and Supply Agreement on May 21, 2008, which was later amended on July 1, 2009 (the "HandyLab-Qiagen License Agreement"). The HandyLab Qiagen License Agreement granted certain rights to Qiagen.

[redacted]. Qiagen N.A. is an affiliate of Qiagen GmbH. [redacted] No later than September

18, 2020, NeuMoDx was acquired by Qiagen and became an affiliate of Qiagen. Therefore, at least as early as September 18, 2020, NeuMoDx became licensed under the HandyLab-Qiagen License Agreement.

[redacted]

Thus, NeuMoDx has a license under all the Asserted Patents and for all Licensed Products since at least as early as September 18, 2020. Qiagen GmbH and Qiagen N.A. have been licensed under the HandyLab-Qiagen License Agreement since 2009. To the extent that any of the Accused Products and/or activities are found to be covered by any claim of any of the Asserted Patents (or utilize any of the Licensed Technology), such Accused Products or activity are covered by the HandyLab-Qiagen License Agreement (i.e., not infringing) since 2009 (as to Qiagen GmbH and Qiagen N.A.) and at least as early as September 18, 2020 (as to NeuMoDx). Plaintiffs are therefore

barred from recovering any damages for any such Accused Products and activities during the licensed periods.

COUNTERCLAIMS

Counterclaim Plaintiffs NeuMoDx Molecular, Inc. ("NeuMoDx"), Qiagen GmbH, and Qiagen North American Holdings, Inc. ("Qiagen NA") (Qiagen GmbH and Qiagen NA shall be referred to herein collectively as "Qiagen) (NeuMoDx, Qiagen Gmbh, and Qiagen NA shall be referred to herein collectively as ("Counterclaim Plaintiffs") counterclaim against Plaintiffs/Counterclaim Defendants Becton, Dickinson and Company, GeneOhm Sciences Canada, Inc. (collectively "BD"), and HandyLab, Inc. ("HandyLab", and collectively with BD, "Counterclaim Defendants") for declaratory judgment and hereby allege as follows:

PARTIES

1. Counterclaim Plaintiff NeuMoDx is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1250 Eisenhower Place, Ann Arbor, Michigan 48108-3281.

2. Counterclaim Plaintiff Qiagen GmbH is a corporation organized and existing under the laws of Germany, with a principal place of business at QIAGEN Strasse 1, 40724 Hilden, Germany.

3. Counterclaim Plaintiff Qiagen North American Holdings, Inc. ("Qiagen NA") is a corporation organized and existing under the laws of California, with a principal place of business at 19300 Germantown Road, Germantown, Maryland 20874.

4. On information and belief, Counterclaim Defendant Becton, Dickinson and Company ("Becton Dickinson" or "BD") is a corporation organized and existing under the laws of New Jersey, with its principal place of business at 1 Becton Drive, Franklin

Lakes, NJ 07417.

5. On information and belief, Counterclaim Defendant HandyLab is a wholly owned subsidiary of Becton Dickinson and a corporation organized and existing under the laws of Delaware, with at least some of the corporation's business activities located in Franklin Lakes, NJ.

6. On information and belief, Counterclaim Defendant GeneOhm Sciences Canada, Inc. is wholly owned subsidiary of Becton Dickinson and a corporation organized and existing under the laws of Canada, with its principal place of business 2555 Boul du Parc-Technologique Québec G1P4S5 Canada.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over NeuMoDx's and Qiagen's counterclaims under at least 28 U.S.C. §§ 1331, 1332, 1338(a), 1367, 2201 and 2202.

8. Counterclaim Defendants are subject to personal jurisdiction in this judicial district because they availed themselves of the jurisdiction of this Court, and engaged in acts giving rise to this controversy in this district.

9. Venue is proper under 28 U.S.C. §§ 1391 and pursuant to Fed. R. Civ. P. 13 because Counterclaim Defendants filed this action in this district.

GENERAL ALLEGATIONS

COUNT I – DECLARATORY JUDGMENT OF NON-INFRINGEMENT

10. NeuMoDx and Qiagen incorporate by reference paragraphs 1-9 of its counterclaims and its affirmative defenses above as though fully set forth herein.

11. Counterclaim Defendants have alleged that NeuMoDx and Qiagen are infringing U.S. Patent Nos. 8,273,308; 8,703,069; 7,998,708; 8,323,900; 8,415,103; 8,709,787; 10,494,663;

10,364,456; 10,443,088; 10,604,788; 10,625,261; 10,625,262; and 10,632,466 (the "Patents-in-Suit). The below paragraphs addressing non-infringement of the asserted patents are exemplary based upon information presently known, and are not intended to limit NeuMoDx's or Qiagen's right to modify the below non-infringement positions or allege that it does not infringe other elements of the identified claims or any other claims of the asserted patents.

12. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1 or 18 of the '308 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '308 patent, including but not limited to:

> [Claim 1] "a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the DNA manipulation zone when amplification of the sample occurs, wherein the only ingress to and egress from the DNA manipulation zone is through the first and second valves, and wherein the computer-controlled heat source is in thermal contact with the DNA manipulation zone"
>
> [Claim 18] "a controller programmed to close the first and second valves to prevent gas and liquid from flowing into or out of the zone when amplification of the sample occurs in the zone, wherein the only ingress to and egress from the zone is through the first and second valves"

13. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1 of the '069 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '069 patent, including but not limited to:

> [Claim 1] "closing the first valve and the second valve such that gas and liquid are prevented from flowing into or out of the DNA manipulation zone"

14. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's

Accused Molecular Diagnostic Products do not infringe claims 1 and 33 of the '708 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '708 patent, including but not limited to:

> [Claim 1] "each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source maintains a substantially uniform temperature throughout the PCR reaction zone and thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone"
>
> [Claim 1] "a processor coupled to the detector and the heat source, configured to control heating of one or more PCR reaction zones by the heat sources"
>
> [Claim 33] "introducing the plurality of samples into a multi-lane microfluidic cartridge, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples"
>
> [Claim 33] amplifying polynucleotides contained with the plurality of samples in the PCR reaction zones while thermal cycling the PCR reaction zones, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone

15. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1, 7 and 20 of the '900 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '900 patent, including but not limited to:

> [Claim 1] "each PCR reaction zone comprising a separately controllable heat source thermally coupled thereto, wherein the heat source thermal cycles the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and maintains a substantially uniform temperature throughout the PCR reaction zone during each cycle"
>
> [Claim 1] "a processor coupled to the detector and the heat sources, configured to control heating of one or more PCR reaction zones by the heat sources"
>
> [Claim 7] "a separately controllable heat source thermally coupled to each PCR reaction zone, wherein the heat source is configured to thermal cycle the PCR reaction zone to carry out PCR on a polynucleotide-containing sample in the PCR reaction zone and to

maintain a substantially uniform temperature throughout the PCR reaction zone during each cycle"

[Claim 7] "a processor coupled to the detector and a plurality of the separately controllable heat sources, configured to control heating of one or more PCR reaction zones by one or more of the plurality of separately controllable heat sources"

[Claim 20] "introducing the plurality of samples into a plurality of multi-lane microfluidic cartridges, wherein each lane comprises a PCR reaction zone configured to permit thermal cycling of a sample independently of the other samples"

[Claim 20] " polynucleotides contained with the plurality of samples in the plurality of PCR reaction zones while thermal cycling the PCR reaction zones and maintaining a substantially uniform temperature throughout each PCR reaction zone during each cycle, at least one PCR reaction zone separately thermally controllable from another PCR reaction zone"

16. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1 and 15 of the '103 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '103 patent including but not limited to:

[Claim 1] "placing the microfluidic cartridge in thermal communication with an array of independent heaters; and amplifying polynucleotides in the plurality of samples by independent application of successive temperature cycles to each sample"

[Claim 15] "introducing the plurality of samples in to a microfluidic cartridge, wherein the cartridge has a plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another;

[Claim 15] "placing the microfluidic cartridge in thermal communication with an array of independent heaters; and amplifying polynucleotides contained within the plurality of samples, by application of successive temperature cycles independently to the reaction chambers"

17. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1, 9 and 10 of the '787 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each

and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '787 patent, including but not limited to:

> [Claim 1] "wherein the isolation effected by the first and the second set of microfluidic valves prevents movement of fluid into and out of the first and the second reaction chambers, wherein the first set of microfluidic valves comprises a first microfluidic valve spatially separated from the first inlet port and a second microfluidic valve spatially separated from the first outlet, and wherein the second set of microfluidic valves comprises a first microfluidic valve spatially separated from the second inlet port and a second microfluidic valve spatially separated from the second outlet, and wherein each of the first and second reaction chambers, the first and second inlet ports, the first and second outlets, and the first and second sets of microfluidic valves are all formed in the microfluidic substrate layer"

> [Claim 9] "wherein the first valve and the second valve are configured to isolate the reaction chamber from the inlet and the vent to prevent movement of fluid into or out of the reaction chamber, wherein the first valve is spatially separated from the inlet and the second valve is spatially separated from the vent, wherein the reaction chamber, the first channel, and the second channel are formed in a first side of the microfluidic substrate, wherein the inlet and the vent are formed in a second side of the microfluidic substrate opposite the first side, and wherein the first valve in each of the plurality of sample lanes is operated independently of any other first valve"

> [Claim 10] "introducing the plurality of samples into the microfluidic cartridge of claim 1, wherein the cartridge has a plurality of reaction chambers comprising the first reaction chamber and the second reaction chamber, the plurality of reaction chambers configured to permit thermal cycling of the plurality of samples independently of one another"

18. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1 or 14 of the '456 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '456 patent, including but not limited to:

> [Claim 1] "retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance , wherein the sample has a volume from 0.5 microliters to 3 milliliters"

> [Claim 1] "wherein the first set of conditions includes a first pH of about 8.5 or less and a first temperature , wherein the first temperature is about 50° C"
>
> [Claim 14] "retaining one or more polynucleotides from a sample on a plurality of binding particles under a first set of conditions, wherein a surface of one or more binding particles is modified with a poly-cationic material, wherein the sample has a volume from 0.5 microliters to 3 milliliters"
>
> [Claim 14] "wherein the first set of conditions includes a first pH of 8.5 or less and a first temperature of about 50° C"
>
> [Claim 14] "wherein the second set of conditions includes increasing the pH by at least three units by addition of a hydroxide solution and increasing the temperature by at least about 40° C. to a second temperature of at least about 90° C"
>
> [Claim 18] "contacting the sample with a plurality of binding particles, the binding particles retaining one or more polynucleotides thereon at a first pH and a first temperature, wherein the sample has a volume from 0.5 microliters to 3 milliliters, wherein the first temperature is about 50° C., wherein a surface of one or more binding particles is modified with a poly-cationic polyimide or polyethyleneimine (PEI)"

19. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1 and 13 of the '088 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '088 patent, including but not limited to:

> [Claim 1] "retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance, wherein the sample has a volume from 0.5 microliters to 3 milliliters"
>
> [Claim 13] "retaining polynucleotides from a sample on a plurality of binding particles in a process chamber under a first set of conditions, wherein the retaining step comprises binding the polynucleotides to the surfaces of the plurality of binding particles comprising a poly-cationic substance; wherein the sample has a volume from 0.5 microliters to 3 milliliters"

20. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1, 22 and 40 of the '788 patent

(and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '788 patent, including but not limited to:

> [Claim 1] "a microfluidic device comprising substrate layers that define a microfluidic network, the microfluidic network comprising a first processing region, the microfluidic device further comprising a waste chamber downstream of the first processing region"
>
> [Claim 1] "a lysing container located external to the substrate layers, wherein the lysing container is configured to receive the biological sample and configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution"
>
> [Claim 1] "a plurality of magnetic binding particles disposed in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof, wherein the plurality of magnetic binding particles are configured to retain at least a portion of the polynucleotides on the surface thereof in the lysate solution at a pH of 8.5 or less"
>
> [Claim 1] "a second processing region comprising PCR reagents, the second processing region configured to receive the eluate solution containing polynucleotides and configured to place the eluate solution in contact with PCR reagents to form a PCR-ready solution"
>
> [Claim 22] "plurality of magnetic binding particles disposed in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof, the lysing container configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution, the plurality of magnetic binding particles configured to retain at least a portion of the polynucleotides on the surface thereof at a pH of about 8.5 or less in the lysate solution"
>
> [Claim 22] "substrate layers defining a microfluidic network that comprises a plurality of microfluidic components including a first processing region, wherein the first processing region is configured to receive, from the lysing container, the lysate solution and the plurality of magnetic binding particles retaining the polynucleotides on the surface thereof; wherein the lysing container is located external to the substrate layers defining the microfluidic network"
>
> [Claim 22] wherein the plurality of magnetic binding particles are configured to release at least a portion of the polynucleotides into an eluate solution when in the presence of the release solution in the first processing region and when heat is applied by a heat source of the plurality of heat sources to the lysate solution and the plurality of magnetic binding particles in the first processing region"

> [Claim 22] "a second processing region comprising PCR reagents and configured to receive the eluate solution containing the eluted polynucleotides to reconstitute the PCR reagents and form a PCR-ready solution"
>
> [Claim 40] "a microfluidic network disposed in a plurality of substrate layers, wherein the microfluidic network comprises a processing region and a detection region"
>
> [Claim 40] "a lysing container located external to the substrate layers, wherein the lysing container is configured to receive the biological sample and configured to place the biological sample in contact with a lysing reagent to release polynucleotides from the biological sample into a lysate solution"
>
> [Claim 40] "a plurality of magnetic binding particles disposed in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surfaces thereof, wherein the plurality of magnetic binding particles are configured to retain at least a portion of the polynucleotides on the surface thereof in the lysate solution at a pH of about 8.5 or less"

21. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1 and 27 of the '663 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '663 patent, including but not limited to:

> [Claim 1] "heating the biological sample in the lysing container to a first temperature between about 30° C. and about 50° C., wherein the polynucleotides are extracted from the biological sample into a lysate solution"
>
> [Claim 1] "contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof, wherein at least a portion of the polynucleotides are retained on the plurality of magnetic binding particles in the lysate solution"
>
> [Claim 1] "transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system, and wherein the lysing container is located external to the microfluidic network"
>
> [Claim 1] "transferring the eluate solution containing polynucleotides to a second processing region in the system, wherein the eluate solution reconstitutes PCR reagents

contained in the second processing region to form a PCR-ready solution"

[Claim 27] "heating the biological sample in the lysing container to a first temperature of about 60° C., wherein the polynucleotides are extracted from the biological sample into a lysate solution"

[Claim 27] "contacting the polynucleotides with a plurality of magnetic binding particles in the lysing container, the plurality of magnetic binding particles comprising polycationic molecules on the surface thereof, wherein at least a portion of the polynucleotides are retained on the plurality of magnetic binding particles in the lysate solution"

[Claim 27] "transferring the lysate solution containing the plurality of magnetic binding particles into a first processing region, wherein the first processing region is within a microfluidic network in the system; and wherein the lysing container is outside of the microfluidic network"

[Claim 27] "transferring the eluate solution containing polynucleotides to a second processing region in the system, wherein the eluate solution reconstitutes PCR reagents contained in the second processing region to form a PCR-ready solution"

22. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1 and 22 of the '261 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '261 patent, including but not limited to:

[Claim 1] "a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples"

[Claim 1] "a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay"

[Claim 1] "the first module further comprising a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality

of process chambers with the magnetic separator when the housing is received in the bay"

[Claim 1] "the first module further comprising a heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the heating assembly configured to heat a solution in the plurality of process chambers to between 50° C. and 85° C., the one or more complementary registration members configured to align the plurality of process chambers with the heater assembly when the housing is received in the bay"

[Claim 22] "a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples, the first module comprising: a bay configured to removably receive a housing comprising a plurality of process chambers that are maintained at a same height relative to one another when the housing is received in the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members configured to receive the housing in a single orientation when the housing is received in the bay"

[Claim 22] "a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay"

[Claim 22] "a magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members further configured to align the plurality of process chambers with the magnetic separator when the housing is received in the bay"

23. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claim 1 of the '262 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '262 patent, including but not limited to:

[Claim 1] "a first module configured to extract nucleic acids from the plurality of nucleic acid-containing samples, the first module comprising: a plurality of sample tubes in the

first module, each sample tube configured to accept a nucleic acid-containing sample of the plurality of nucleic-acid containing samples"

[Claim 1] "a plurality of process chambers in the first module, wherein a process chamber of the plurality of process chambers is spatially separate from, and corresponds to, a sample tube of the plurality of sample tubes, the plurality of process chambers maintained at a same height relative to one another in the first module"

[Claim 1] "a magnetic separator configured to apply a magnetic force to at least one process chamber of the plurality of process chambers in the first module"

24. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, NeuMoDx's Accused Molecular Diagnostic Products do not infringe claims 1 and 23 of the '466 patent (and any claims depending therefrom), either directly or indirectly, because they do not include each and every element, either literally or by application of the doctrine of equivalents, of any valid claim of the '466 patent, including but not limited to:

[Claim 1] "extracting nucleic acids from the plurality of nucleic acid-containing samples in a first module and amplifying the nucleic acid extracted from the plurality of nucleic acid-containing samples simultaneously in a second module using a system comprising a liquid dispenser and a bay, the first module comprising a magnetic separator and a heating assembly, wherein extracting the nucleic acids comprises"

[Claim 1] "removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator of the first module positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly of the first module positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the heater assembly when the housing is received in the bay"

[Claim 1] "dispensing, using the liquid dispenser, at least a portion of the plurality of

nucleic acid-containing samples and a plurality of magnetic binding particles into the plurality of process chambers when the housing is received in the bay"

[Claim 1] "moving the liquid dispenser between the plurality of nucleic acid-containing samples and the plurality of process chambers when the housing is received in the bay"

[Claim 1] "dispensing the nucleic acid extracted from the plurality of nucleic-acid containing samples into the second module"

[Claim 23] "extracting nucleic acids from the plurality of nucleic acid-containing samples in a first module using a system comprising a liquid dispenser, the first module comprising a bay, a magnetic separator, and a heating assembly, wherein extracting the nucleic acids comprises"

[Claim 23] "removably receiving a housing comprising a plurality of process chambers in the bay, the plurality of process chambers maintained at a same height relative to one another as the housing is received in and removed from the bay, the plurality of process chambers aligned along a first axis when the housing is received in the bay, the bay comprising one or more complementary registration members that receive the housing in a single orientation when the housing is received in the bay, the magnetic separator positioned to apply a magnetic force to a first side of the plurality of process chambers when the housing is received in the bay, the magnetic separator comprising one or more magnets aligned along a second axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the magnetic separator when the housing is received in the bay, the heating assembly positioned adjacent to a second side of the plurality of process chambers opposite the first side when the housing is received in the bay, the heater assembly comprising one or more heaters aligned along a third axis parallel to the first axis when the housing is received in the bay, the one or more complementary registration members aligning the plurality of process chambers with the heater assembly when the housing is received in the bay"

[Claim 23] "dispensing, using the liquid dispenser, at least a portion of the plurality of nucleic acid-containing samples and a plurality of magnetic binding particles into the plurality of process chambers when the housing is received in the bay"

[Claim 23] "moving the liquid dispenser between the plurality of nucleic acid-containing samples and the plurality of process chambers when the housing is received in the bay"

[Claim 23] "dispensing the nucleic acid extracted from the plurality of nucleic-acid containing samples into a second module, the second module configured to receive a multi-lane microfluidic cartridge configured to simultaneously amplify the nucleic acid extracted from the plurality of nucleic acid-containing samples"

25. NeuMoDx's Accused Molecular Diagnostic Products also do not infringe any

claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents, either directly or indirectly, because the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid and thus cannot be infringed, for the reasons set forth in the following paragraphs contained in Count 2 of NeuMoDx's and Qiagen's Counterclaim.

26. By reason of Counterclaim Defendants' charges of patent infringement, and NeuMoDx's and Qiagen's denial of those charges, there exists a justiciable controversy between Counterclaim Defendants and Counterclaim Plaintiffs with respect to Counterclaim Defendants' assertion of infringement of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents and NeuMoDx's and Qiagen's denial thereof.

27. NeuMoDx and Qiagen are entitled to a judgment under Rule 57 of the Federal Rules of Civil Procedure and 28 U.S.C. § 2201 declaring that NeuMoDx and Qiagen are not infringing and have not infringed the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents and granting to NeuMoDx and Qiagen all other declaratory relief to which it may be entitled.

COUNT 2 – DECLARATORY JUDGMENT OF INVALIDITY

28. NeuMoDx and Qiagen incorporate by reference the above paragraphs of its counterclaims and its affirmative defenses above as though fully set forth herein.

29. Counterclaim Defendants allege that NeuMoDx and Qiagen infringe one or more claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents and that the patents are valid and enforceable.

30. Counterclaim Plaintiffs deny that the Accused Products infringe the Patents-in-Suit.

31. If the Patents-in-Suit are construed broadly enough to cover the Accused Products, then the Counterclaim Plaintiffs are licensed under the HandyLab-Qiagen License Agreement.

32. Counterclaim Defendants have nevertheless maintained their infringement claims against Counterclaim Plaintiffs in violation of the HandyLab-Qiagen License Agreement, claiming that the Patents-in-Suit are not licensed.

33. NeuMoDx alleges that the claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid because they fail to comply with one or more requirements of the Patent Laws of the United States, 35 U.S.C. §1 et seq., including without limitation, §§ 101, 102, 103 or 112, as the claims of the patents are anticipated, obvious and/or indefinite, and that there is prior art and other evidence that anticipates or renders obvious the claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents.

34. Qiagen alleges that the claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid because they fail to comply with one or more requirements of the Patent Laws of the United States, 35 U.S.C. §1 et seq., including without limitation, §§ 101, 102, 103 or 112, as the claims of the patents are anticipated, obvious and/or indefinite, and that there is prior art and other evidence that anticipates or renders obvious the claims of the '308, '069, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents.

35. Based upon NeuMoDx's ongoing investigation, NeuMoDx asserts that the claims of the '708 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Anderson, U.S. Patent No. 6,168,948; Ganesan, U.S. Patent App. Pub. No.

US2005/0084424; Mian, WO 97/21090; Southgate, WO 97/27324; Chang, WO 98/38487; Northrup, WO 94/05414; Yoon, U.S. Patent App. Pub. No. US2005/0112754; Handique, U.S. Patent No. 7,010,391; Wu, U.S. Provisional Patent App. No. 60/491,269; Jensen, U.S. Patent App. Pub. No. 2006/0246493; Ganesan, U.S. Provisional Patent App. No. 60/491,539; Southgate, U.S. Patent No. 5,863,502; Ganesan, U.S. Provisional Patent App. No. 60/491,264; and Oh, "World-to-chip microfluidic interface with built-in valves for multichamber chip-based PCR assays", Lab Chip, 5, (2005):845-50. The claims of the '708 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '708 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

36. Based upon Qiagen's ongoing investigation, Qiagen asserts that the claims of the '708 patent are invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

37. Based upon NeuMoDx's ongoing investigation, NeuMoDx asserts that the claims of the '900 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Anderson, U.S. Patent No. 6,168,948; Ganesan, U.S. Patent App. Pub. No. US2005/0084424; Pourahmadi, WO 99/33559; Mian, WO 97/21090; Southgate, WO 97/27324; Terbrueggen, WO 02/243864; Northrup, WO 94/05414; Yoon, U.S. Patent App. Pub. No. US2005/0112754; Handique, U.S. Patent No. 7,010,391; Wu, U.S. Provisional Patent App. No. 60/491,269; Jensen, U.S. Patent App. Pub. No. 2006/0246493; Ganesan, U.S. Provisional Patent

App. No. 60/491,539; Southgate, U.S. Patent No. 5,863,502; and Oh, "World-to-chip microfluidic interface with built-in valves for multichamber chip-based PCR assays", Lab Chip, 5, (2005):845-50. The claims of the '900 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '900 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

38. Based upon Qiagen's ongoing investigation, Qiagen asserts that the claims of the '900 patent are invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

39. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '308 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references including but not limited to: Pourahmadi, WO 99/33559; Chang, WO 98/38487; Mian, WO 97/21090; Anderson, U.S. Patent No. 6,168,948; Northrup, WO 94/05414; Southgate WO 97/27324; Kellogg, WO 00/78455; Kellogg, WO 98/07019; Peterson, WO 0073412; and McMillan, "Application of Advanced Microfluidics and Rapid PCR to Analysis of Microbial Targets", *Proceedings of the 8th International Symposium on Microbial Ecology*, 1999, 13 pgs. The claims of the '308 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of

the '308 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

40. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '069 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references including but not limited to: Pourahmadi, WO 99/33559; Chang, WO 98/38487; Anderson, U.S. Patent No. 6,168,948; Northrup, WO 94/05414; Southgate WO 97/27324; Peterson, WO 0073412; and McMillan, "Application of Advanced Microfluidics and Rapid PCR to Analysis of Microbial Targets", *Proceedings of the 8th International Symposium on Microbial Ecology*, 1999, 13 pgs. The claims of the '069 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '069 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

41. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '103 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references including but not limited to: Handique, U.S. Patent App. Pub. No. 2007/0292941; Handique, U.S. Provisional Appl. No. 60/859,284; Ganesan, U.S. Patent App. Pub. No. 2005/0084424; Jensen, U.S. Patent App. Pub. No. 2006/0246493; Kellogg, WO 00/78455; Yoon, U.S. Patent App. Pub. No. US 2005/0112754; Handique, U.S. Provisional Appl. No. 60/726,066; Mian, U.S. Patent No. 6,319,469; Handique, U.S. Patent No. 7,010,391; Ganesan, U.S. Provisional Patent Appl. No.

60/491,264; and Handique U.S. Patent App. Pub. No. 2007/0184547. The claims of the '103 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '103 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

42. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '787 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references including but not limited to: Ganesan, U.S. Patent App. Pub. No. 2005/0084424; Jensen, U.S. Patent App. Pub. No. 2006/0246493; Björnson, U.S. Patent No. 6,827,906; Kellogg, WO 00/78455; Yoon, U.S. Patent App. Pub. No. 2005/0112754; Zou, U.S. Patent No. 6,509,186; Zou, U.S. Patent No. 6,762,049; Handique, U.S. Provisional Appl. No. 60/726,066; Parunak, U.S. Provisional Appl. No. 60/553,553; Wu, U.S. Provisional Appl. No. 60/491,269; Handique, U.S. Patent No. 7,010,391; Ganesan, U.S. Provisional Patent Appl. No. 60/491,539; and Handique U.S. Patent App. Pub. No. 2007/0184547. The claims of the '787 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '787 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's and Qiagen's March 17, 2021 invalidity contentions.

43. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '456 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Backus, EP 0707077; Baker, WO 00/75623; Baker, U.S. Patent App. Pub. No. 2001/0018513; Sutton, U.S. Patent No. 5,147,777; Smith, U.S. Patent No. 6,310,199; and Belly, WO 00/66783. The claims of the '456 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '456 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

44. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '088 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Backus, EP 0707077; Baker, U.S. Patent App. Pub. No. 2001/0018513; Bamdad, U.S. Patent App. Pub. No. 2002/0086443; Owen, U.S. Patent No. 4,795,698; Smith, U.S. Patent No. 6,310,199; and Belly, WO 00/66783. The claims of the '088 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '088 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

45. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '788 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Backus, EP 0707077; Baker, U.S. Patent App. Pub. No. 2001/0018513; Belly, WO 00/66783; Bamdad, U.S. Patent App. Pub. No. 2002/0086443; Southgate WO 97/27324; Pourahmadi, WO 99/33559; Chang, WO 98/38487; Oultram, WO 01/92569; and Knapp, U.S. Patent No. 6,670,133. The claims of the '788 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '788 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

46. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '663 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Backus, EP 0707077; Baker, U.S. Patent App. Pub. No. 2001/0018513; Belly, WO 00/66783; Bamdad, U.S. Patent App. Pub. No. 2002/0086443; Southgate WO 97/27324; Pourahmadi, WO 99/33559; Oultram, WO 01/92569; and Brown, WO 96/00228. The claims of the '663 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of

the '663 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

47. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '261 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Hansen, U.S. Patent No. 6,672,458; Safar, U.S. Patent App. Pub. No. 2006/0081539; Andrews, U.S. Patent No. 6,043,880; Cathcart, U.S. Patent No. 5,443,791; Pourahmadi, WO 99/33559; Chang, WO 98/38487; Collis, U.S. Patent No. 5,973,138; Jensen, U.S. Patent App. Pub. No. 2006/0246493; Duong, WO 2001//54813; Bickmore, U.S. Patent App. Pub. No. 2006/0152727; Hsieih, U.S. Patent No. 7,122,799; Kopf-Sill, U.S. Patent App. Pub. No. 2001/0045358; and Oh, "World-to-chip microfluidic interface with built-in valves for multichamber chip-based PCR assays", Lab Chip, 5, (2005):845-50. The claims of the '261 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '261 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

48. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '262 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including, including but not limited to: Hansen, U.S. Patent No. 6,672,458; Safar, U.S. Patent App. Pub. No. 2006/0081539; Andrews, U.S. Patent No. 6,043,880; Cathcart, U.S. Patent No. 5,443,791;

Southgate, U.S. Patent No. 5,863,502; Pourahmadi, WO 99/33559; Chang, WO 98/38487; Zurek, U.S. Patent No. 5,576,218; Jensen, U.S. Patent App. Pub. No. 2006/0246493; Duong, WO 2001//54813; Bickmore, U.S. Patent App. Pub. No. 2006/0152727; Hsieih, U.S. Patent No. 7,122,799; Kopf-Sill, U.S. Patent App. Pub. No. 2001/0045358; and Oh, "World-to-chip microfluidic interface with built-in valves for multichamber chip-based PCR assays", Lab Chip, 5, (2005):845-50. The claims of the '262 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions. The claims of the '262 patent are also invalid based on any 35 U.S.C. §112 defenses set forth in NeuMoDx's March 17, 2021 invalidity contentions.

49. Based upon NeuMoDx's and Qiagen's ongoing investigation to date, the claims of the '466 patent are invalid pursuant to §§ 102 and/or 103 at least because the claimed subject matter is anticipated by and/or obvious based upon one or more prior art references, including but not limited to: Hansen, U.S. Patent No. 6,672,458; Safar, U.S. Patent App. Pub. No. 2006/0081539; Andrews, U.S. Patent No. 6,043,880; Cathcart, U.S. Patent No. 5,443,791; Pourahmadi, WO 99/33559; Zurek, U.S. Patent No. 5,576,218; Collis, U.S. Patent No. 5,973,138; Jensen, U.S. Patent App. Pub. No. 2006/0246493; Duong, WO 2001/54813; Bickmore, U.S. Patent App. Pub. No. 2006/0152727; Hsieih, U.S. Patent No. 7,122,799; Kopf-Sill, U.S. Patent App. Pub. No. 2001/0045358; and Oh, "World-to-chip microfluidic interface with built-in valves for multichamber chip-based PCR assays", Lab Chip, 5, (2005):845-50. The claims of the '466 patent are invalid in view of these prior art references and for the reasons set forth in NeuMoDx's invalidity contentions that were served on Counterclaim Defendants on March 17, 2021, and which

are incorporated herein by reference, as well as in view of any additional background prior art cited in NeuMoDx's March 17, 2021 invalidity contentions.

50. An actual and justiciable controversy exists between Counterclaim Defendants and NeuMoDx and Qiagen regarding the invalidity of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents.

51. NeuMoDx and Qiagen are entitled to a judgment under Rule 57 of the Federal Rules of Civil Procedure and 28 U.S.C. § 2201 declaring that the claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid.

COUNT III – BREACH OF CONTRACT

52. NeuMoDx incorporates by reference the above paragraphs of the counterclaims and the affirmative defenses above as though fully set forth herein.

53. In late 2011, Williams and Brahmasandra contacted senior executives at Becton Dickinson and shared Williams' intentions to actively pursue, with the support of venture capital, a startup nucleic acid testing systems company.

54. Brahmasandra informed Becton Dickinson that he was interested in joining MSC, but that he was prevented from doing so because of the non-compete agreement with Becton Dickinson.

55. Brahmasandra requested a waiver of his non-compete agreement to work with Williams at MSC to develop a nucleic acid-based system for performing rapid identification.

56. On February 23, 2012, Becton Dickinson and Brahmasandra entered into an "Amendment to Employment Agreement." Becton Dickinson agreed that "Employee (Brahmasandra) shall be permitted to engage in any activity relating to nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification contemplated by

Molecular Systems Corporation."

57. Becton Dickinson also agreed that the "Proposed Business (MSC) shall not be deemed to Compete with or be Competitive with the Company (HandyLab) or any of its Affiliates for the purpose of this Agreement."

58. MSC is an intended third party beneficiary of the February 23, 2012 Agreement.

59. There was consideration for the Amended Agreement. Brahmasandra was required to "use "commercially reasonable efforts" to schedule a meeting with "representatives of BD's exploratory technology group for the purpose of providing additional information about the Proposed Business, subject to the execution and delivery of a customary non-disclosure agreement…".

60. Brahmasandra complied with his obligations. On several occasions during 2012 and 2013, MSC, which changed its name in 2012 to NeuMoDx, shared its business purposes, system architecture, technology, patents/patent applications and financing/financing plans with Becton Dickinson.

61. In July 2013, NeuMoDx inquired with a senior Becton Dickinson executive about Becton Dickinson's interest in participating in a venture financing round of NeuMoDx. NeuMoDx provided a two-page summary of its system and technology and informed Becton Dickinson that NeuMoDx "had developed technology combining the best attributes of both integrated cartridge and microplate-based, liquid handling system, with the resulting platform to offer improved ease of use, lower costs, and higher performance compared to other nucleic acid testing systems."

62. After 2013, NeuMoDx met with representatives of Becton Dickinson at least annually at industry trade shows at which NeuMoDx provided Becton Dickinson with

demonstrations of the NeuMoDx products and answered questions about the technology. During the parties' meetings, NeuMoDx shared its technology, including confidential aspects of its technology, with Becton Dickinson.

63. Becton Dickinson has now breached the Amended Agreement with Brahmasandra and MSC/NeuMoDx, the intended third party beneficiary of the Agreement, by suing NeuMoDx for the very nucleic acid based testing as it relates to the nucleic acid based system for performing rapid identification activity that Becton Dickinson agreed Brahmasandra and MSC/NeuMoDx could engage in.

64. NeuMoDx has been harmed and suffered damages as a direct and proximate result of Becton Dickinson's breach of contract, including but limited to the time, resources, attorney's fees, costs and expenses incurred in defending the present lawsuit filed by Becton Dickinson against NeuMoDx, as well as actual damages, reputational damages and lost opportunities resulting from Becton Dickinson's breach.

COUNT IV – DECLARATORY JUDGMENT OF NO TERMINATION OF LICENSE AGREEMENT

65. Counterclaim Plaintiffs incorporate by reference the above paragraphs of the counterclaims and the affirmative defenses above as though fully set forth herein.

66. Counterclaim Plaintiff Qiagen GmbH and Counterclaim Defendant HandyLab entered into a License and Supply Agreement on May 21, 2008, which was later amended on July 1, 2009 (the "HandyLab-Qiagen License Agreement"). [redacted]. Based on information and belief, Counterclaim Defendant BD is an affiliate of HandyLab.

67. On January 7, 2021, Counterclaim Defendants sent a letter to Qiagen GmbH (the

"Letter"). Exhibit A (under seal). Counterclaim Defendants stated in the Letter that [redacted]

68. Counterclaim Defendants contend that the Patents-in-Suit [redacted] under the HandyLab-Qiagen License Agreement to Qiagen GmbH, Qiagen N.A., or NeuMoDx.

69. Counterclaim Defendants nevertheless said in the Letter, [redacted]. *Id*. In a letter dated January 25, 2021, Counterclaim Plaintiff Qiagen GmbH sought clarification about whether [redacted] Exhibit B (under seal). Counterclaim Defendant Becton Dickinson responded by letter dated February 12, 2021, stating, [redacted] Exhibit C (under seal). There is an actual case or controversy between the parties ripe for resolution.

70. [redacted]

[redacted] *See* Exhibit X.

71. Counterclaim Defendants have not terminated the HandyLab-Qiagen License Agreement. [redacted].

72. Counterclaim Defendants stated to Qiagen that [redacted]

73. Moreover, Sections 4.5, 7.1, and 14 of the HandyLab-Qiagen License Agreement [redacted] Thus, regardless of whether the Patents-in-Suit are licensed under the HandyLab-Qiagen License Agreement, the Counterclaim Defendants cannot terminate the HandyLab-Qiagen License Agreement under Section 8.1(i) for the reasons stated in the Letter. Moreover, the reasons stated in the Letter cannot amount to a *material* breach of any representation, warranty or duty.

74. Section 4.5 is legally unenforceable to the extent it [redacted], and they cannot provide a basis to terminate. The HandyLab-Qiagen

License Agreement was not entered into to resolve any actual or threatened litigation. Counterclaim Plaintiffs cannot materially breach a legally unenforceable provision.

75. Counterclaim Defendants have stated that Section 7.1 required a party to the HandyLab-Qiagen License Agreement to [redacted] No Counterclaim Defendant notified Qiagen GmbH (or any other Qiagen affiliate) of any threatened infringement by NeuMoDx prior to Counterclaim Defendants filing this lawsuit against Counterclaim Plaintiff NeuMoDx. Any alleged breach of Section 7.1 by Counterclaim Defendants against Counterclaim Plaintiffs was not material.

76. No Counterclaim Plaintiff materially breached any representation or warranty or duty of the HandyLab-Qiagen License Agreement. And no Counterclaim Defendant provided any Counterclaim Plaintiff with [redacted] days prior written notice of an opportunity to cure any alleged material breach of a representation or warranty or duty of the HandyLab-Qiagen License Agreement. No Counterclaim Defendant can terminate the HandyLab-Qiagen License Agreement under Section 8.1(i).

77. If permitted to terminate the HandyLab-Qiagen License Agreement, Counterclaim Plaintiffs would be harmed and suffer damages as a direct and proximate result of Counterclaim Defendants wrongful termination and breach of contract, including actual damages, reputational damages, and lost opportunities resulting from Counterclaim Defendants' actions.

RESERVATIONS OF RIGHTS

The above affirmative defenses and counterclaims are based upon incomplete information because NeuMoDx's and Qiagen's discovery and investigation of the claims, counterclaims and defenses in this action are continuing. Therefore, NeuMoDx and Qiagen reserve the right to supplement and/or amend such defenses and/or counterclaims if and when further information becomes available.

PRAYER FOR RELIEF

WHEREFORE, NeuMoDx and Qiagen prays for entry of a judgment:

1. Dismissing the Complaint with prejudice;

2. Declaring that Defendants are not infringing, and have not infringed, directly, contributorily, by inducement, or under §271(f) any claim of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents, either literally or under the doctrine of equivalents;

3. Declaring that the claims of the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents are invalid under 35 U.S.C. §§ 102, 103, and /or 112;

4. Declaring that this case is "exceptional" under 35 U.S.C. § 285 and awarding Defendants their reasonable attorney's fees and costs;

5. Enjoining Counterclaim Defendants from enforcing the '308, '069, '708, '900, '103, '787, '456, '088, '788, '663, '261, '262 and '466 patents against NeuMoDx and Qiagen or any of NeuMoDx's or Qiagen's current or future customers;

6. Declaring that Becton Dickinson has breached the February 23, 2012, Becton Dickinson "Amendment to Employment Agreement" by filing the present lawsuit;

7. Awarding NeuMoDx damages for Becton Dickinson's breach of February 23, 2012, Becton Dickinson "Amendment to Employment Agreement", including but not limited to the time, resources, attorney's fees, costs and expenses incurred in defending the present lawsuit filed by Counterclaim Defendants against NeuMoDx, as well as actual damages, reputational damages, lost opportunities resulting from Becton Dickinson's breach, and pre and post-judgment interest.

8. Declaring that HandyLab did not terminate and cannot terminate the HandyLab-Qiagen License Agreement and enjoining any such attempt.

9. Awarding Defendants damages for Becton Dickinson's improper attempt to terminate the HandyLab-Qiagen License Agreement, including but not limited to the time, resources, attorney's fees, costs and expenses incurred in defending the present lawsuit, as well as actual damages, reputational damages, lost opportunities resulting from Becton Dickinson's improper termination and breach, and pre and post-judgment interest.

10. Awarding to NeuMoDx and Qiagen any further necessary and proper relief under 28 U.S.C. § 2202;

11. Directing Counterclaim Defendants to pay all costs and expenses incurred by NeuMoDx and Qiagen in this action, including reasonable attorneys' fees; and

12. Such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, NeuMoDx and Qiagen hereby demand a trial by jury on all issues so triable.

Dated: March 18, 2021

Respectfully submitted,

FARNAN LLP

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EXHIBIT A

FILED UNDER SEAL

REDACTED

EXHIBIT B

FILED UNDER SEAL

REDACTED

EXHIBIT C

FILED UNDER SEAL

REDACTED